REMARKS/ARGUMENTS

Claims 1, 3-4, 6-7, and 41, as amended, and new claims 42-50 are pending in this application for the Examiner's review and consideration. Claims 10-32 are withdrawn and claims 2, 5, 8-9, and 33-40 are canceled. Applicants appreciate the Examiner's recognition that claim 41 is patentable.

Claim 1 was amended to more clearly recite the invention. Specifically, claim 1 was amended to recite that the isolated and purified compound is the heptasaccharide "linked to one amino acid or an oligopeptide" (Specification at ¶ [0010] and ¶ [0060], Example 4).[1] Claims 3-4 and 7 were simply amended to have proper antecedent basis, *i.e.*, to recite the "compound as defined in claim 1." Claim 4 was amended to more clearly recite the invention. Claim 4 was also amended to spell out the genus *Campylobacter*. Specifically, claim 4 was amended to recite the compound "obtained from a glycoprotein that is isolated and purified from a bacterium selected from *Campylobacter jejuni* and *Campylobacter coli*." New claims 42 and 45-49 are directed to an immunogenic conjugate comprising the compound of claim 1 or the heptasaccharide of allowed claim 41 (Specification at ¶ [0013] and [0074]). New claims 43 and 44 depend from allowed claim 41 and recite the "isolated and purified heptasaccharide as defined in claim 41 obtained from a glycoprotein that is isolated and purified from *Campylobacter jejuni* or *Campylobacter coli*" (Specification at ¶ [0061], Example 5) and a "pharmaceutical composition comprising the isolated and purified heptasaccharide of claim 41 and a physiologically acceptable carrier" (Specification at ¶ [0013]), respectively. New claims 48 and 49 are directed to the subject matter of canceled claims 8 and 9. New claim 50 recites the embodiment wherein the heptasaccharide is linked to one amino acid. No new matter is added by these claim amendments so that their entry at this time is warranted.

Interview Summary

Applicants appreciate the courtesy extended to Applicants' attorney, Paul E. Dietze, in an in-person interview on April 16, 2008. Applicants' attorney discussed the differences between the claimed invention and the disclosure of the prior art, in particular US Patent No. 5,470,958

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[1] All references to the specification refer to the paragraphs in the published application, *i.e.*, US 2006/0165728.

("Blaser"). Applicants' attorney explained to the Examiner that the prior art does not disclose an isolated and purified compound that is a heptasaccharide of formula GalNAc-a1,4-GalNAc-a1,4-[Glc-β1,3]GalNAc-a1,4-GalNAc-a1,4-GalNAc-a1,3-Bac, wherein Bac is 2,4-diacetamido-2,4,6-trideoxy-D-gluco-pyranose linked to one amino acid or an oligopeptide. The differences between the claimed invention and the disclosure in the prior art is further described in the remarks set forth below. The remarks provided below are in substantial accordance with the discussions held during the interview.

The Rejections Under 35 U.S.C. § 102(b)[2]

As the Examiner is aware, in order to establish anticipation under 35 U.S.C. § 102(b) a prior art reference must disclose each and every limitation either expressly or inherently in a single prior art reference. *See Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F. 3d 1354, 1360 (Fed. Cir. 1998); *Standard Havens Prods., Inc. v. Gencor Indus. Inc.*, 953 F.2d 1360, 1369 (Fed. Cir. 1991); *Jamesbury Corp. v. Litton Indus. Products*, 756 F. 2d 1556 (Fed. Cir. 1985); *American Hospital Supply v. Travenol Labs.*, 745 F.2d 1 (Fed. Cir. 1984). There must be no difference between the claimed invention and the reference disclosure as viewed by one of ordinary skill in the art. *See Scripps Clinic & Research Fdn. v. Genentech*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *Carella v. Starlight Archery and Proline Co.*, 804 F.2d 135, 138 (Fed. Cir. 1986); *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444 (Fed. Cir. 1984). Put another way, "[a] claim is anticipated and therefore invalid only when a single prior art reference discloses *each and every limitation of a claim.*" *Glaxo Inc. v. Novapharm Ltd.*, 52 F.3d 1043, 1047, *cert. denied*, 116 S. Ct. 516 (1995) (*citations omitted*). In addition, to anticipate, the reference must also enable one of skill in the art to make and use the claimed invention. *In re Donohue*, 766 F.2d, 532, 533 (Fed. Cir. (1985), *see also Net MoneyIn v. Verisign,* Docket no. 2007-1565) (Fed. Cir. 2008).

Applicants respectfully submit that the prior art cited by the Examiner does not anticipate the claims, as amended, because, as discussed below, the prior art does not disclose each and every feature of the claims.

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[2] Applicants note that several rejected claims have been canceled, amended, or replaced with new claims. Thus Applicants will address the rejection in view of the currently pending claims.

The Rejection of the Claims as Anticipated by Szymanski in Light of Guerry

The Examiner maintained the rejection of claims 1-4, 7-8, 37, 39, 33-35 under 35 U.S.C. § 102(b) as anticipated by Szymanski *et al.*, *Evidence for a System of General Protein Glycosylation in Campylobacter jejuni*, Molecular Biology, 32(5), 1022-1030 (1999) ("Szymanski") in light of evidence provided by US 2007/0065461 ("Guerry") for the reasons set forth on pages 3-5 of the Office Action. Specifically, the Examiner asserts that "the compound of claim 1 is an isolated heptasaccharide [ ] that is conjugated to an amino acid [ ] and further comprises an immunoconjugate" (Office Action at p. 4, para. 15). The Examiner goes on to state that:

> The compound of Szymanski et al comprises the heptasaccharide of claim 1 (in light of evidence provided by Guerry et al) linked to an amino acid (asparagine) in an immunoconjugate (PEB3 shown in isolated and purified form, together with the glycan [ ]. The pharmaceutically accepted carrier was water [ ], this composition anticipates the instant claims because it was NOT deglycosolated and was an isolated and purified heptasaccharide immunoconjugated, the conjugate being PEB protein, linked to the heptasaccharide through Asparagine. PEB3 is highly immunogenic, a immunoconjugate [ ] that comprises the instant heptasaccharide linked through an amino acid the immunoconjugate sequence.

(Office Action at p. 4-5, para. 16). Applicants respectfully traverse.

Szymanski in light of Guerry does not anticipate the claims, as amended, because Szymanski does not disclose a heptasaccharide that is "linked to one amino acid or an oligopeptide," as recited in independent claim 1, as amended. In contrast, Szymanski, at best, discloses a heptasaccharide that is linked to a native protein. A native protein is not "one amino acid or an oligopeptide." Although the "one amino acid or an oligopeptide" may, for example, be obtained from a native protein, one of ordinary skill in the art, reading the specification, would readily understand that the phrase "one amino acid or an oligopeptide" does not encompass a native protein.

Similarly, one of ordinary skill in the art would readily understand the phrase "an immunogenic conjugate" does not encompass the native protein but only encompasses the isolated and purified heptasaccharide of claim 41 (claim 42) or the compound of claim 1 (claim 47) conjugated to a molecule to provide a compound *other* than the native protein. Indeed, it

would make no sense to obtain the isolated and purified heptasaccharide of claim 41 or compound of claim 1 from, for example, degradation of a protein, and to then reconstruct the protein and call it "an immunogenic conjugate." To construe the phrase "an immunogenic conjugate" to encompass the native protein would be an unreasonable and strained construction. Applicants respectfully submit that, contrary to the assertion by the Examiner, PEB3 is not an immunogenic conjugate as that term is used by one of ordinary skill in the art.

Because Szymanski in light of Guerry does not disclose a heptasaccharide that is "linked to one amino acid or an oligopeptide" and does not disclose an immunogenic conjugate comprising the heptasaccharide or heptasaccharide linked to one amino acid or an oligopeptide, Szymanski in light of Guerry does not anticipate the claims.

For the reasons set forth above, Applicant respectfully request that the rejection of claims under 35 U.S.C. § 102(b) as anticipated by Szymanski in light of Guerry be reconsidered and withdrawn.

The Rejection of the Claims as Anticipated by Blaser in Light of Rangarajan and The Rejection of the Claims as Anticipated by Pei in Light of Rangarajan

Claims 1-4, 7-9, 33-35, 37, and 39-40 were rejected under 35 U.S.C. § 102(b) as anticipated by US Patent No. 5,470,958 ("Blaser") in light of evidence provided by Rangarajan *et al., Structural Context for Protein N-Glycosylation in Bacteria: The Structure of PEB3, an Adhesin from Campylobacter jejuni*, Protein Science, 16:990-995 (2007) ("Rangarajan") for the reasons set forth on pages 7-8 of the Office Action. The Examiner asserts that Blaser inherently anticipates the claims.

Claims 1-4, 7-8, 33-35, 37, and 39 were rejected under 35 U.S.C. § 102(b) as anticipated by Pei *et al., Identification, Purification, and Characterization of Major Antigenic Proteins of Campylobacter jejuni*, J. Bio. Chem., 265:25, 16363-16369 (1991) ("Pei") in light of evidence provided by Rangarajan for the reasons set forth on pages 8-9 of the Office Action. The Examiner asserts that Pei inherently anticipates the claims. Applicants respectfully traverse.

Blaser in light of Rangarajan and Pei in light of Rangarajan, like Szymanski in light of Guerry, at best, only discloses a heptasaccharide that is linked to a native protein. In contrast,

independent claim 1, as amended, recites a heptasaccharide that is "linked to one amino acid or an oligopeptide." As discussed above, one of ordinary skill in the art, reading the specification, would clearly understand that the phrase "one amino acid or an oligopeptide" does not encompass the native protein. Similarly, as also discussed above, one of ordinary skill in the art would readily understand the phrase "an immunogenic conjugate" to not encompass the native protein but only to encompasses the isolated and purified heptasaccharide of claim 41 (claim 42) or compound of claim 1 (claim 47) conjugated to some *other* molecule. Applicants respectfully submit that, contrary to the assertion by the Examiner, PEB3 is not an immunogenic conjugate as that term is used by one of ordinary skill in the art.

Applicants further discuss herein the disclosure of Blaser because during the Interview the Examiner indicated that she felt that Blaser was the closest prior art. In particular, the Examiner suggested that Applicants consider the disclosure in Blaser at col. 3, line 38 to column 4, line 6 and the amino acid sequence disclosed in Table 2 at columns 9 and 10. Thus, each of these disclosures is specifically discussed. Blaser discloses PEB3 at columns 3 to 4. Blaser discloses that the term PEB3 "includes antigenic fragments of the natural protein whether derived from the natural protein or synthetically or recombinantly produced" (Blaser at col. 3, lines 53-56). There is, however, no disclosure or even a recognition in Blaser that the PEB3 disclosed therein is bound to or might be bound to a heptasaccharide. Although Rangarajan (which is not prior art) later discloses that the natural PEB3 protein is glycosylated, there is no disclosure, or even a recognition, in Blaser that the natural PEB3 protein disclosed therein is bound to a heptasaccharide. Accordingly, although Blaser discloses that the term PEB3 "includes antigenic fragments of the natural protein whether derived from the natural protein or synthetically or recombinantly produced" (Blaser at col. 3, lines 53-56), Blaser could not have disclose a fragment that is bound to a heptasaccharide, much less "[a]n isolated and purified compound that is a heptasaccharide of formula GalNAc-a1,4-GalNAc-a1,4-[Glc-β1,3]GalNAc-a1,4-GalNAc-a1,4-GalNAc-a1,3-Bac, wherein Bac is 2,4-diacetamido-2,4,6-trideoxy-D-gluco-pyranose linked to one amino acid or an oligopeptide," as recited in independent claim 1. Blaser could not disclose the compound of claim 1 because Blaser was not even aware that the natural PEB3 protein could be bound to a heptasaccharide. The broad disclosure in Blaser that the natural PEB3 protein disclosed therein, like any other protein, can be fragmented, without any

recognition that the protein can be bound to a heptasaccharide, is not a disclosure of, or even a suggestion of, "[a]n isolated and purified compound that is a heptasaccharide of formula GalNAc-a1,4-GalNAc-a1,4-[Glc-β1,3]GalNAc-a1,4-GalNAc-a1,4-GalNAc-a1,3-Bac, wherein Bac is 2,4-diacetamido-2,4,6-trideoxy-D-gluco-pyranose linked to one amino acid or an oligopeptide," as recited in independent claim 1. Clearly, not even being aware that the natural PEB3 protein could be bound to a heptasaccharide, Blaser can not enable a fragment of PEB3 protein that contains a heptasaccharide, much less the compound recited in claim 1. Indeed, Applicants note that there are no Examples in Blaser of a fragment of the natural PEB3 protein that could potentially contain a heptasaccharide.

Blaser does disclose in Table 2 of columns 9 and 10 the first 34 amino acid residues of the amino terminus of the natural PEB3 protein. This disclosure of the first 34 amino acid residues, however, is also not a disclosure of a fragment that contains a heptasaccharide, much less the compound claimed in claim 1. The sequence disclosed in Table 2 is simply the results of analyzing the natural PEB3 protein using an amino acid analyzer. Amino acid analysis using an amino acid analyzer would not detect a saccharide residue, much less a heptasaccharide residue, or provide any suggestion that the natural PEB3 protein could be bound to a heptasaccharide. Indeed, amino acid analysis subjects the protein to conditions that would cleave any saccharide groups that are attached to the protein. Moreover, even if the conditions used to determine the amino acid sequence did not cleave saccharide groups from the protein, the amino acids that are formed from the amino acid analysis are never isolated or purified, as required by claim 1. Blaser simply does not disclose or suggest the compound of claim 1.

Because neither Blaser nor Pei in light of Rangarajan disclose a heptasaccharide that is "linked to one amino acid or an oligopeptide" or an immunogenic conjugate comprising the heptasaccharide or heptasaccharide linked to one amino acid or an oligopeptide, Blaser in light of Rangarajan and Pei in light of do not anticipate the claims.

For the reasons set forth above, Applicant respectfully request that the rejection of claims under 35 U.S.C. § 102(b) as anticipated by Blaser in light of Rangarajan and Pei in light of Rangarajan be reconsidered and withdrawn.

New Grounds of Rejection

The Examiner asserted that the abstract of the disclosure, submitted on August 7, 2008, included the title of the application and only the abstract should be presented. Applicants submit herewith a new abstract without the title. Applicants respectfully submit that the newly submitted Amendment addresses the rejection.

The Double Patenting Objection

Claims 2-4 were objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of claims 33-35. The objection is rendered moot by the cancellation of claims 2, and 33-35.

CONCLUSION

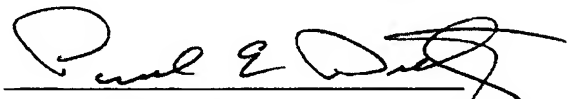
It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicant respectfully requests a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite eventual allowance of the claims.

A Petition for Extension of Time to extend the time for responding by two (2) month from February 26, 2009 to April 26, 2009, with provision for the applicable fee, is submitted concurrently herewith.

No other fee is believed to be due for this submission. Should any additional fees be required, please charge the required fees to Townsend and Townsend and Crew LLP deposit account no. 201430.

Date: April 24, 2009

Respectfully submitted,



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